(Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which [comprises] consists essentially of administering topically a number of times daily to the site on the mammal of the disease or condition over a prolonged period of time a non-toxic dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, [(]to treat and resolve the disease, condition or lesion[)], non-toxic ([]to the patient[)] dosage amount of a drug which inhibits prostaglandin synthesis (component (1)[)] and an effective dosage amount comprising at least [50-]30-60 mg of a form of hyaluronic acid [and/or] selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof [and/or] [fragments, and/or sub-units] [thereof] (component (2)[)] sufficient to transport [(facilitate the transport of)] the drug (component (1)[)] into the skin and/or exposed tissue ([]including any scar tissue[)] at the site of the disease or condition to be treated to block prostaglandin synthesis.

8. (Thrice Amended) The method of Claim 6 wherein the form of hyaluronic acid [and/or pharmaceutically acceptable salts thereof and/or] [fragments, and/or sub-units] [thereof] is selected from the group consisting of hyaluronic acid [or] and a pharmaceutically acceptable salt thereof having a molecular weight less than 750,000 daltons.

10. (Thrice Amended) The method of Claim 9 wherein the NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, aceytylsalicylic acid and Flunixin.

11. (Fourth Amendment) The method of Claim 9 wherein

[(i) the concentration of component (2) equals or exceeds a concentration of 1 1/2% by weight of the dosage amount;]

[(ii) the concentration of component (1) equals or exceeds a concentration of 1% by weight of the dosage amount;]

[(iii) component (2) equals or exceeds 1 1/2% by weight of the dosage amount and component (1) equals or exceeds 1% by weight of the dosage amount;]

[(iv) component (2) equals or exceeds 1 1/2% by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount;]

[(v) component (2) equals or is less than 3% by weight of the dosage amount and component (1) equals or exceeds 1% by weight of the dosage amount;]

[(vi) component (2) equals or exceeds 1 1/2% by weight of the dosage amount and component (1) equals or exceeds 1% by weight but is less than or equal to 5% by weight of the dosage amount;]

[(vii) component (2) equals or is less than 3% by weight of the dosage amount and component (1) equals or exceeds

1% by weight but is less than or equal to 5% by weight of the dosage amount;]

[(viii) component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of the dosage amount and component 1) equals or exceeds 1% by weight of the dosage amount;]

[(ix) component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight or the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount; and]

[(x)] component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount but equals to or greater than 1% by weight of the dosage amount.

13. (Twice Amended) [The] A method [of Claim 11 wherein] [the concentration of component (1) is set out in subparagraph (ii)] of treating basal cell carcinoma which consists essentially of administering a number of times daily topically to the site on the mammal of the basal cell carcinoma over a prolonged period of time a non-toxic effective dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, to treat and resolve the disease, condition or lesion, non-toxic to the patient, dosage amount of a non-steroidal anti-inflammatory drug (NSAID) which inhibits prostaglandin

synthesis (component 1) and an effective dosage amount comrising a form of hyaluronic acid selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof (component 2) sufficient to transport the drug (component 1) into the skin and/or exposed tissue, including any scar tissue, at the site of the disease or condition to be treated to block prostaglandin synthesis and wherein component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount but equals to or greater than 1% by weight of the dosage amount.

14. (Thrice Amended) The method of Claim [11] 13 wherein [the concentration of components (1) and (2) are those set out in subparagraph (iii)] the treatment is applied daily for a number of weeks.

15. (Fourth Amendment) The method of Claim [11] 13 wherein [the concentration of components (1) and (2) are those set out in subparagraph (iv)] the form of hyaluronic acid is selected from the group consisting of hyaluronic acid and a pharmaceutically acceptable salt thereof, having a molecular weight less than 750,000 daltons.

16. (Twice Amended) The method of Claim [11] 13 wherein the [concentration of components (1) and (2) are those set out in subparagraph (v)] the NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, aceytylsalicylic acid and Flunixin.

17. (Twice Amended) The method of Claim [11] 13 wherein [the concentration of components (1) and (2) are those set out in subparagraph (vi)] component (2) is sodium hyaluronate having a molecular weight less than about

750,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

Please cancel Claims 18, 19, 20, and 26.

REMARKS

Of the Claims being examined by Examiner Krikorian, Claims 6 to 17 inclusive remain in the case to be examined. No new subject matter was added by the amendments made to the Claims above. Particularly, all of the subject matter has been described. Having regard to Claims 11 and 12, the subject matter thereof (namely the concentrations) is disclosed in the Formulations 1 to 9 described in the Application.

In response to the Official Action and particularly with respect to the objections under 35 USC §112, Examiner Krikorian is requested to refer to Applicants' disclosure of its invention in its Application. Applicants discuss at page 12, line 7, the malfunction of macrophages or their putitive block is due to excessive prostaglandin which excessive prostaglandin can be adjusted by, among other substances, non-steroidal anti-inflammatory drugs. The substances including non-steroidal anti-inflammatory drugs could alter the response to neoplastic cells. However, the use of NSAIDS cause major toxicity in terms of gastro-intestinal, neurological and other areas (page 12, lines 23-24). Because of these prohibitive side-effects, the drugs including NSAIDS are not used alone because they produce prohibitive side-effects in human subjects (page 13, lines 1-2). There thereafter follows a discussion of how malignant cell sneaks by the immune surveillance mechanism and cause the production of prostaglandin